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APPEAL 5X
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PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Peter Colin Weston BURT

Serial Number: 09/379,492

Group Art Unit: 3754

Filed: August 23, 1999

Examiner: Derakshani

For: Aerosol Dispenser With Ultrasonically Welded Closure and Method of Making

BRIEF ON APPEAL

Assistant Commissioner for Patents
Washington, D.C. 20231

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TECHNOLOGY CENTER R3700

Sir:

This brief on appeal is submitted in triplicate. The required appeal fee for submission with the brief has already been paid on May 22, 2000, with the previous brief filed in this application. The Commissioner is hereby authorized to charge any further fee necessary to this appeal to Deposit Account No. 02-0200.

I. REAL PARTY IN INTEREST

The real party in interest is the Assignee of record, Glaxo Group Limited.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences with respect to the claimed invention which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal known to appellant, appellant's legal representative or assignee.

III. STATUS OF THE CLAIMS

This application contains 40 claims. Claims 1-19 and 36 have been canceled from the application and are no longer pending.

Claims 20-35 and 37-40 are pending and are the claims on appeal. Claims 20-35 and 37-40 stand finally rejected.

IV. STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendment was filed after final rejection.

V. SUMMARY OF INVENTION

The present invention (though not exclusively) is concerned with metered dose medicament aerosols, for example, metered dose inhalers, (page 1, lines 1-5). Such inhalers are used in inhalation therapy for asthmatic patients and the like. Thus, the metered dose is administered into the lungs of the patient, and it is imperative that the material being metered is not contaminated by gasket material (page 1, lines 25-28) and there is minimum leakage (page 2, lines 1-4) and moisture ingress (page 4, line 2).

The present invention provides an aerosol dispenser which comprises a body, a closure sealed to the body and means for dispensing material from the interior of the dispenser, wherein the closure is welded to the body by a metal-to-metal weld. Preferably the welding is carried out ultrasonically; page 2, lines 7-11.

Also included is a method of assembling an aerosol dispenser comprising a metal body, a metal closure, and means for dispensing material from the interior of the dispenser, wherein the closure is welded to the body by a metal-to-metal seal; page 2, lines 12-15. This method includes avoiding exposing the weld joint to a peel force; page 7, lines 3-7.

VI. ISSUES

The issue on appeal is whether the combination of references relied upon in the Final Rejection renders the rejected claims *prima facie* obvious under 35 U.S.C. 103(a).

VII. GROUPING OF THE CLAIMS

The claims as grouped in the Final Rejection do not stand or fall together.

VIII. ARGUMENT

Previous Board of Appeals Decision

The Final Rejection here on appeal contains three obviousness rejections. The primary reference in each rejection is the Goncalves reference which was referred to in the Board of Appeals' decision of May 15, 2001, reversing the Examiner's prior rejections then on appeal. The Board noted that the Goncalves reference discloses an aerosol container having a metal body 2, a closure 3, the body and closure being joined by welding together interengaging flanges 7, 9 of each of them, using a laser beam and referring to Figure 2. The Board notes that given this disclosure it should be ascertained whether it would have been obvious in view of Welter, to join the body and closure of the Goncalves container by means of ultrasonic welding instead of laser welding. (Emphasis added.) The Board drew no conclusion with respect to the obviousness of the claimed invention over this reference but left this determination to the Examiner.

The rejections over the prior art now on appeal should also be reversed since the combinations of references do not render the claimed subject matter *prima facie* obvious.

Basic Requirements of a Prima Facies Case of Obviousness

The appellant believes that the criteria set forth in the MPEP provides guidance in determining the issue of obviousness of the claims on appeal over the prior art of record.

MPEP § 2143 Basic Requirements of a Prima Facie Case of Obviousness

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

MPEP §2143.03 All Claim Limitations Must Be Taught or Suggested

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

MPEP § 2144.08 Office Personnel Should Consider All Rebuttal Argument

This section provides that office personnel should consider all rebuttal argument and evidence present by applicant and the citation of *In re Soni* for error in not considering evidence presented in the specification.

Arguments For Reversal

The combination of the Goncalves reference and the Welter reference does not render *prima facie* obvious the rejected claims because there is no motivation in the prior art to combine the Goncalves reference with the Welter reference. The only teaching of this is found in Appellant's specification which may not be relied upon as a teaching reference. In this regard, the teachings of the references as a whole, as they would be understood by one of ordinary skill in the art, must be taken into consideration and "obvious to try" is not the standard of obviousness under 35 U.S.C. 103.

The Goncalves reference is in French and this discussion is based upon the translation kindly provided by the Examiner in the Official Action of July 27, 2001. Any discussion with respect to a page number is a reference to the page number of this translation.

As noted on page 2 of Goncalves, the present invention pertains to pressurized containers of the "aerosol bomb" type, used for example for packaging and distribution of cosmetic or cleaning products. These containers are provided with a dispensing valve allowing the user, by operating a push button that is connected to the valve, to cause the ejection of the product to be dispensed. The product to be dispensed is further characterized on page 3 as a low-cost product such as cleaning products. There is no suggestion that the container may be used to dispense an aerosol medicament which is an object of the present invention and as specifically claimed, see claims 26 and 38 to 40. The requirements for an aerosol dispenser for a medicament are clearly different from for a low-cost product as described in Goncalves as would be appreciated by one of ordinary skill in the art to which the invention pertains. Such requirements include accuracy of the metered dose and stability of the medicament which includes preventing leakage in or out of the dispenser, see figure 6 of the present application.

As discussed on page 4 of Goncalves, it is noted that containers that have a wide upper opening have problems associated with forming such containers by

crimping of the base to the dome and it is the object of the Goncalves invention to overcome this problem by the use of laser welding which allows one to avoid crimping which has presented some problems. Goncalves avoids crimping by welding by means of a pencil laser beam which, as would be appreciated by one of ordinary skill in the art, is completely different from welding by ultrasonic means as required by the presently claimed invention. There is nothing in the references which teach the equivalence of these two types of welding.

The difference between ultrasonic and laser welding would be appreciated by one of ordinary skill in the art who would not substitute ultrasonic welding for laser welding as taught by Goncalves in the Goncalves invention since one of the objects of Goncalves in using laser welding is to eliminate the apparatus for crimping. That is, excessive equipment surrounding the opening. However, ultrasonic welding requires additional equipment in the form of a horn and anvil which would lead one of ordinary skill in the art away from substituting ultrasonic welding for welding by means of a pencil laser beam as taught by Goncalves since ultrasonic welding requires equipment, a horn and anvil, to surround the opening. Goncalves does not suggest that any type of welding can be used, but is specific to welding with a pencil laser beam for the avoidance of equipment surrounding the opening. This teaching cannot be ignored in determining the motivation to modify the reference because this teaching is part of the prior art as a whole.

Similarly, Welter does not teach the equivalence of welding by ultrasound and welding with a pencil laser beam. Absent any teaching of the equivalence of ultrasonic welding, which requires a welding horn and an anvil, and welding with a pencil laser beam, the rejection is based upon hindsight or at most "obvious to try," which in neither case, establishes a *prima facie* case of obviousness for the presently claimed invention.

Neither reference teaches that the flanges are outwardly directed and flat which is a requirement of claim 22 which facilitates the process.

Welter points out that ultrasonic welding is used where high temperatures would be impractical. Welding with a pencil laser beam is not suggested as an

alternative. Moreover, Welter states that high frequency vibrations are used in place of heat. That is, ultrasonic welding produces only very localized heating in the region of the weld itself, which enables the can to be filled before the closure is secured thereto since it reduces the risk of the substance to be dispensed being undesirably heated (see page 3, lines 13 to 17). This would not be possible with other heat intensive welding techniques.

The method of ultrasonic welding does not require special preparation of the surfaces to be welded and each closure can be welded to a container very quickly in a single compression stroke using the apparatus depicted in Figure 4 (1/4 second per dispenser) which leads to an efficient manufacturing process.

The ultrasonic weld so produced is strong and results in enhanced performance of aerosol dispensers with regard to leakage and moisture ingress over conventional crimped dispensers (see page 4, lines 1 to 22 together with the test results presented in Tables 1 and 2 and Figures 5 and 6).

The secondary reference to Welter relates to a variable weighted ultrasonic welding horn and anvil which may be used for several purposes, including the joining of metals or plastics. It further teaches that ultrasonic welding is often used in applications where high temperatures would be impractical, such as in connecting fine wires to microchips, sealing plastic bags and hermetically closing toothpaste or similar tubes. There is absolutely no suggestion of using ultrasonic welding for sealing high pressure aerosol dispensers to form a metal to metal weld as required by the claims on appeal. There must be some teaching in the references of record which lead one of ordinary skill in the art to combine the references to arrive at appellants' claimed invention. Appellants' disclosure may not be used as a teaching reference to combine the references in the rejection. Clearly, in the present case, in view of the absence of any disclosure suggesting the application of ultrasound welding technique to aerosol dispensers, the rejection is untenable.

Absent some teaching of equivalency in the prior art for ultrasonic welding and welding with a pencil laser beam the rejection of the claims over this combination of references should be reversed.

The rejection of claims 23-25, 30 and 32-36 under 35 U.S.C. 103 as being unpatentable over Goncalves in view of Welter as applied to claim 20 above, and further in view of Mascia et al. should be reversed for the reasons discussed above and for the following reasons.

In the Final Rejection it is noted that Goncalves lacks the flanges rolled and crimped together and that Mascia et al. shows a closure 16 and body 12 having flat flanges which are rolled and crimped together. It is then urged that it would have been obvious to one of ordinary skill in the art to have modified the Goncalves flanges with flanges which are rolled and crimped together as taught by Mascia et al. as an alternative equivalent means for attaching a closure to the body by an aerosol dispenser. This aspect of the rejection is clearly in error and should be reversed. Clearly, Goncalves fairly teaches to one of ordinary skill in the art that rolling and crimping are not the equivalent of laser welding. The whole object of the Goncalves reference is to avoid rolling and crimping and the additional apparatus associated therewith. Any modification to combine the teachings of the references is based upon Applicant's specification and impermissible hindsight.

Clearly, one of ordinary skill in the art would not combine the references as suggested in the Official Action since Goncalves expressly teaches to avoid crimping of the precise closure referred to in the Mascia et al reference. It is the very purpose of the Goncalves reference to avoid crimping. Any attempt to modify the Goncalves primary reference to include crimping or the use of additional equipment ignores the explicit teaching in Goncalves that the object of the invention is to avoid crimping of the closure to the container body and the additional apparatus associated therewith. Thus, Goncalves teaches away from crimping and is not combinable with the secondary prior art cited in the rejections.

Moreover, there is no recognition of the problem solved by this further aspect of the present invention to avoid exposing the welded joint to a peel force as stated at page 7 of Appellant's specification. The weld joint produced by the pencil laser beam apparently satisfactorily seals the closure and there is no recognition of the

problem, let alone the solution of the present invention. Accordingly, it is most respectfully requested that this rejection be reversed.

The rejection of claim 26, 38 and 40 under 35 U.S.C. 103 as unpatentable over Goncalves in view of Welter as applied to claim 20 above and further in view of Ryden should also be reversed for the reason discussed above.

Applicant agrees with the Examiner's statement that Goncalves lacks the aerosol dispenser as an inhaler. Again, Goncalves is directed to a completely different type of aerosol which relates to cleaning fluids and cosmetics. Compare the shape and contents of the container in Ryden with that of Goncalves. As would be appreciated by one of ordinary skill in the art, inhalers for dispensing a medicament are completely different in structure and effect from an aerosol dispenser for a cleaning product. These differences would not be ignored by one of ordinary skill in the art and there is no motivation by one of ordinary skill in the art to add an aerosol medicament to a container which is clearly described as being directed to cosmetics and cleaners and other low-cost production items. The requirements for metering a medicament and the formation of an aerosol formulation as well as the stability (see Figure 6 of Appellant's specification and the corresponding discussion) of the products are all factors which need to be considered and which would not be ignored by one of ordinary skill in the art. Therefore, the combination suggested by the Examiner is not suggested by the references but is based upon Appellant's disclosure which is improper hindsight.

None of the prior art relied upon in this rejection in any way recognizes the problem solved by the present invention, let alone the solution. Thus, there is no suggestion in the primary reference of the ultrasonic metal to metal weld sealed in accordance with the claims on appeal. This improvement resulted from the discovery by Appellant of the problem associated with the prior art seals and including leakage in inhalers. This recognition by Appellant forms part of the invention as a whole and must be taken into consideration in evaluating the patentability of the claims on appeal over the prior art.

The Ryden reference in no way overcomes the deficiencies of the Goncalves and Welter references. The Ryden reference describes the administration of medicinal agents by inhalation from a container with a propellant. The container is described at line 47 of column 1 as a pressure tight container of metal or other material and the container is provided with a valve. The container is a separate unit from the dispenser and the Ryden invention relates to locking the dispenser to the container. There is no discussion of ultrasonically welding the closure to the body of the container or a container having such a closure and containing a medicament as required by claim 36 on appeal.

Accordingly, it is most respectfully requested that this rejection be reversed.

IX. CONCLUSION

In view of the above arguments, the rejections of the claims on appeal should not be sustained. The Final Rejection should be reversed and the application passed to issue.

Respectfully submitted,

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APPENDIX

CLAIMS ON APPEAL

20. An aerosol dispenser comprising a body, a closure sealed to the body, and means for dispensing material from the interior of the dispenser, wherein the closure is welded ultrasonically to the body by a metal-to-metal weld.

21. An aerosol dispenser according to claim 20, wherein the metal-to-metal weld is between annular flanges on the body and closure extending circumferentially about the axis of the body and closure.

22. An aerosol dispenser according to claim 21, wherein the flanges are outwardly directed and flat.

23. An aerosol dispenser according to claim 21 wherein the flanges are axially directed and cylindrical.

24. An aerosol dispenser according to claim 21 wherein the flanges are welded, rolled and crimped together.

25. An aerosol dispenser according to claim 21 wherein one of the flanges is of greater width than the other, and wherein the outer edge portion of the wider flange forms a U within which the outer edge portion of the narrower flange is located, both said edge portions extending generally parallel to the adjacent wall of the body.

26. An aerosol dispenser according to claim 20, which is an inhaler and contains an aerosol medicament.

27. A method of assembling an aerosol dispenser comprising a metal body, a metal closure, and means for dispensing material from the interior of the

dispenser, wherein the closure is welded ultrasonically to the body by a metal-to-metal seal.

28. A method of assembling an aerosol dispenser according to claim 27, wherein the closure, which comprises an annular flange extending circumferentially about its axis, is positioned at the open end of and coaxially with the body, which comprises a complementary annular flange extending circumferentially about its axis, such that the flanges are parallel and in contact with each other.

29. A method of assembling an aerosol dispenser according to claim 28, wherein the flanges are welded together by means of an ultrasonic welding head which is brought into communication with the flanges and moved circumferentially along the flanges to create a substantially continuous weld between the flanges until a complete revolution about the axis of the closure and body has been performed.

30. A method of assembling an aerosol dispenser according to claim 28 wherein the flanges are outwardly directed and flat.

31. A method of assembling an aerosol dispenser according to claim 29, whereby the ultrasonic welding head causes relative vibration between the flanges in a direction which is radial with respect to the said axis.

32. A method of assembling an aerosol dispenser according to claim 28 wherein the flanges are bent to lie in a substantially axial direction after the flanges have been welded together.

33. A method of assembling an aerosol dispenser according to claim 28 wherein the said flanges are axially directed and cylindrical.

34. A method of assembling an aerosol dispenser according to claim 33 wherein the ultrasonic welding head causes relative vibration between the flanges in an axial direction.

35. A method of assembling an aerosol dispenser according to claim 28 wherein one of the said flanges is of greater width than the other and after the flanges have been welded together the wider flange is rolled and crimped around the other flange.

37. A method of assembling an aerosol dispenser according to claim 28 wherein an aerosol medicament is added to the container and pressurized and the flanges are rolled and crimped after they have been welded together.

38. An aerosol dispenser as claimed in claim 37, wherein the aerosol dispenser is an inhaler containing an aerosol medicament.

39. A method of assembling an aerosol dispenser according to claim 28 wherein the and the flanges are rolled and crimped after they have been welded together and the aerosol dispenser is an inhaler and an aerosol medicament is added to the dispenser and pressurized.

40. A method of assembling an aerosol dispenser according to claim 35 wherein the aerosol dispenser is an inhaler and an aerosol medicament is added to the dispenser and pressurized.